

## Covered Entities Guide for Public Users

### Submitting a Change or Termination Request

This guide describes how to submit an online request to change some of covered entity's information or to terminate a covered entity that is no longer participating in the 340B Drug Pricing Plan. Such requests can only be submitted for covered entities actively participating in the OPA 340B Program, including covered entities with a future participation start date.

Once you start, you must complete the process. If you quit before submitting change or termination request, your changes will be lost. Data cannot be saved until the request is submitted.

Change requests **cannot** be submitted if:

- The covered entity has been terminated and is no longer participating in 340B Program
- The covered entity already has a change request pending OPA approval.
- The covered entity is undergoing recertification and Authorizing Official has already recertified, but OPA has not reviewed yet.

### Major Sections in This Guide

- [Change Requests](#) (page 4)
- [Change Requests during Recertification](#) (page 8)
- [Termination Requests](#) (page 9)
- [Authorizing and Submitting the Request](#) (page 10)

### Initiating a Change/Termination Request

Follow these steps to submit an online change or termination request:

- 1) On the 340B Database home page, click **Change Request** in the “*What Would You Like to Do?*” section.



**Note:** You can also select **Submit a Change/Termination Request** from the **Change Request** tab in the menu at the top of the home page. The system will jump directly to the **Search Criteria – Instructions** page (see Step 3).

- 2) On the **Change Request** screen, click **Submit a Change/Termination Request**.

**CHANGE REQUEST**

**Covered Entities**

☒ **Submit a Change/Termination Request**

**Contract Pharmacies**

☐ **Request Contract Terminations**

- 3) **340B ID:** Enter the entity ID number and click the **Search** button.

**Search Criteria**

**Instructions:**

Please insert a valid 340B ID in the field below for the entity which you would like to make changes/updates. You will receive an automated confirmation e-mail after submitting your request; the Authorizing Official on record for your covered entity will receive a separate e-mail with further instructions for accepting or rejecting the proposed changes or accepting or rejecting the termination request. You will now be able to submit a Change Request to only change the Authorizing Official when your entity is undergoing Rectification. For more information about submitting a change request, please refer to the [user guide](#).

Please note: if your entity is undergoing recertification, you will only be able to request a change in Authorizing Official.

\* **340B ID:** SCH050336-2

**Note:** You can search for an entity using a partial ID of at least four alphanumeric characters. Search results will retrieve all covered entities whose ID number begin with the identical character string.

- 4) Select the desired entity and click the **Continue** button.

**Search Results:**

**Instructions: Select a single Covered Entity.**

The number of rows returned: 6 Rows/Page: 200

Select One	340B ID	Entity Type	Entity Name	Subdivision Name	Address	City	State
<input type="radio"/>	SCH050336-26	SCH	SONORA COMMUNITY HOSPITAL DBA SONORA REGIONAL MEDICAL CENTER	Sonora Regional Surgery Center	905 Morningstar Drive	Sonora	CA
<input checked="" type="radio"/>	SCH050336-27	SCH	SONORA COMMUNITY HOSPITAL DBA SONORA REGIONAL MEDICAL CTR	Yosemite Joint Replacement	680 GUZZI LANE SUITE 102	SONORA	CA

Page 1 of 1

1

**Note:** For instructions on customizing the presentation of the **Search Results** page, refer to [Searching, Viewing, and Exporting Covered Entity Data](#).

- 5) The **Contact Information** page for the entity displays showing contact information the Authorizing Official and Primary Contact.

SCH050335-27 - SONORA COMMUNITY HOSPITAL DBA SONORA REGIONAL MEDICAL CENTER

**Contact Information**

You will be able to update the Authorizing Official information as needed during the Termination or Change Request submission process. Please select Continue to select a Termination or Change Request.

**Authorizing Official**  
**Name:** Andrew Jahn  
**Title:** PRESIDENT/CEO  
**Phone:** 209-538-5012 **Ext:**  
**Email:** \*\*\*\*\*@\*\*\*\*.\*\*\*

**Primary Contact**  
**Name:** Ashley Pedroni  
**Title:** 340B Program Specialist  
**Phone:** 209-538-3704 **Ext:**  
**Email:** \*\*\*\*\*@\*\*\*\*.\*\*\*

Continue Cancel

- 6) Click the **Continue** button. The **Request Type** page displays.

**Request Type**

What kind of request do you want to make?

☐ Termination Request  
☒ Change Request

Continue Cancel

**Note:** If the entity already has an approved termination request with a future-effective date, the system will skip over this screen and go directly to the Change Request screens to allow you to make changes to the entity information.

- 7) Select the appropriate option to identify whether you are submitting a **Change Request** or a **Termination Request**.
- 8) Click the **Continue** button.

## Change Requests

For a change request, the **Covered Entity Details** page is displayed. Click any of the tabs at the top of the page to change the entity's name or EIN, address information, Medicaid/orphan drug information, or contact information.

Note: If the entity is undergoing recertification and if the authorizing official has not recertified yet, then the entity will only be able to change the Contact information during a change request.

### Details Tab

- 1) Edit the information on this tab if you need to update the entity's name, subdivision name, or Employee Information Number.

SCH050335-27 - SONORA COMMUNITY HOSPITAL DBA SONORA REGIONAL MEDICAL CTR

Details Addresses Medicaid / Orphan Drug Contacts

**Covered Entity Details**

\*Entity Name: SONORA COMMUNITY HOSPITAL DBA SONORA REGIONAL MEDICAL CTR

Entity Sub-Division Name: Yosemite Joint Replacement

Entity Type: Sole Community Hospital

\*Employer Identification Number: 94-1415069 (Enter the registrant's EIN if a sub-grantee/sub-recipient)

Medicare Provider Number: 050335 (only required for hospital entity types)  
(if known/applicable)

☒ Yes, I would like to register Medicare Cost Report outpatient facilities for 340B Program.

Update Cancel

## Addresses Tab

- 2) Edit the information on this tab if you need to update the entity's street address or billing address or edit, delete, or add shipping addresses. Selecting the appropriate check box lets you make the billing and/or shipping address the same as the street address.

SCH050335-27 - SONORA COMMUNITY HOSPITAL DBA SONORA REGIONAL MEDICAL CENTER

Details **Addresses** Medicaid / Orphan Drug Contacts

**Covered Entity Address**

Street Address (PO Box Not Allowed)

\*Address Line 1: 680 GUZZI LANE SUITE 102

Address Line 2:

\*City: SONORA

\*State: California

\*Zip: 95370

☐ Billing Address Same as Street Address

**Billing Address**

\*Organization Name: SONORA COMMUNITY HOSPITAL DBA

\*Address Line 1: 1000 GREENLEY ROAD

Address Line 2:

\*City: SONORA

\*State: California

\*Zip: 95370

☐ Shipping Address Same as Street Address

**Shipping Address (PO Box Not Allowed)**

**Shipping Address 1** [Edit](#) [Delete](#) [Add](#)

SONORA COMMUNITY HOSPITAL DBA SONORA REGIONAL  
1000 GREENLEY ROAD  
SONORA, CA 95370

Update Cancel

## Medicaid/Orphan Drug Information

- 3) Edit the information on this tab if you need to modify the entity's Medicaid billing information or orphan drug exclusion election. Clicking the **Edit** link allows you to change the Medicaid Billing Information and Orphan Drug Exclusion options.

SCH050335-27 - SONORA COMMUNITY HOSPITAL DBA SONORA REGIONAL MEDICAL CENTER

Details Addresses **Medicaid / Orphan Drug** Contacts

**Medicaid Billing** [Edit](#)

**Medicaid Billing Information**

You must answer the following question regarding Medicaid Billing:

Will you bill Medicaid for drugs purchased at 340B drug price? ☐ Yes ☒ No

**Orphan Drug Exclusion**

Once a hospital subject to the orphan drug exclusion (i.e., critical access hospitals, free-standing cancer hospitals, sole community hospitals and rural referral centers) is enrolled in the 340B Program, it may change its decision regarding whether or not to purchase all orphan drugs outside of the 340B Program on a quarterly basis by notifying HRSA. This information will be verified during the annual recertification process. Please choose one of the following:

☐ The hospital will purchase orphan drugs under the 340B Program and maintain auditable records to demonstrate compliance with the orphan drug exclusion.

☒ The hospital cannot or does not wish to maintain auditable records regarding compliance with the orphan drugs exclusion and will purchase all orphan drugs outside of the 340B Program regardless of the indication for which the drug is used and will not use a Group Purchasing Organization (GPO) to purchase those drugs if the hospital is a free-standing cancer hospital.

Note: Any change to your selection will be effective on the first day of the quarter following approval by OPA.

[Update](#) [Cancel](#)

Responding **Yes** to the **“Will you bill Medicaid for drugs purchased at 340B drug price?”** question expands the **Medicaid Billing Information** section of the tab to allow you to add, edit, or delete Medicaid and NPI number.

[Continue](#) [Undo](#)

**Medicaid Billing Information**

You must answer the following question regarding Medicaid Billing:

Will you bill Medicaid for drugs purchased at 340B drug price? ☒ Yes ☐ No

**Medicaid Exclusion Tutorial**

**Medicaid Number(s):** [Add](#)

Medicaid Number	State		
050446	CA	<a href="#">Edit</a>	<a href="#">Delete</a>

**NPI Number(s):** [Add](#)

NPI Number		
1427004099	<a href="#">Edit</a>	<a href="#">Delete</a>

Clicking **Continue** saves any changes you have made. Clicking **Undo** cancels your changes.

## Contact Information

- 4) Edit the information on this tab if you need to change the entity's Authorizing Official or Primary Contact.

SCH050335-27 - SONORA COMMUNITY HOSPITAL DBA SONORA REGIONAL MEDICAL CENTER

Details Addresses Medicaid / Orphan Drug **Contacts**

### Contact Information

Please select the Edit link to update the Authorizing Official information if it has changed.

**Authorizing Official** [Edit](#)

**Name:** Andrew Jahn  
**Title:** PRESIDENT/CEO  
**Phone:** 209-536-5012 **Ext:**  
**Email:** \*\*\*\*\*@\*\*\*\*.\*\*\*

**Primary Contact**

**\*Name:** Ashley Pedroni  
**\*Title:** 340B Program Specialist  
**\*Phone:** 209-536-3704 **Ext:**  
(xxx-xxx-xxxx)  
**\*Email:** \*\*\*\*\*@\*\*\*\*.\*\*\*

The primary contact should be someone employed by the Covered Entity  
Note: An email is on file for this contact. To change, enter a new email address.

Clicking the **Edit** link allows you to change the name, title, and contact information for the Authorizing Official. Selecting the **"Make Primary Contact Information same as Authorizing Official"** check box allows you to copy the Authorizing Official's information to the Primary Contact if they are the same person.

SCH050335-27 - SONORA COMMUNITY HOSPITAL DBA SONORA REGIONAL MEDICAL CENTER

Details Addresses Medicaid / Orphan Drug **Contacts**

### Contact Information

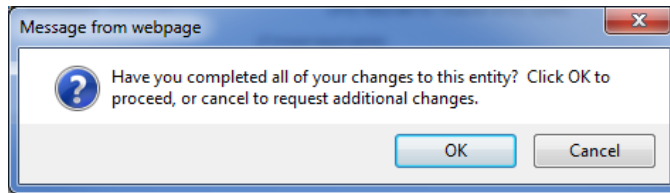
The authorizing Official represents the covered entity and must be fully authorized to legally bind the covered entity. For many non-hospital covered entities, the authorizing Official is the grantee of record (e.g., Project Director) based upon Federal funding streams. For hospital covered entities, the authorizing Official is usually the CEO/CFO/COO/President/Vice President or equivalent.

**Authorizing Official**

**\*Name:** Andrew Jahn x  
**\*Title:** PRESIDENT/CEO  
**\*Phone:** 209-536-5012 **Ext:**  
(xxx-xxx-xxxx)  
**\*Email:** \*\*\*\*\*@\*\*\*\*.\*\*\*

☐ Make Primary Contact Information same as Authorizing Official

- 5) When finished making your updates, click the  button at the bottom of the page. A screen message asks if you are done updating entity data.

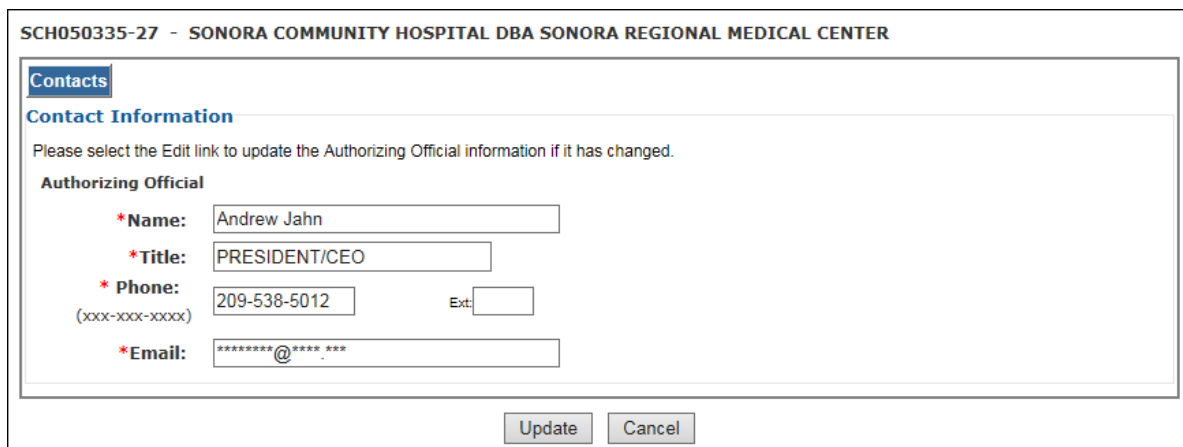


- 6) Click the  button.

You will now affirm that an Authorizing Official will need to review and confirm the proposed changes. . Refer to [Authorizing and Submitting the Request](#) (page 10) for instructions.

## Change Requests during Recertification

If the entity is undergoing recertification and the Authorizing Official (AO) has not yet certified or decertified the entity, the system will display only the **Contacts** tab, and only the AO fields will be editable.



After the AO contact information is changed, the system will send the Change Request Notification email to the new AO for approval of the change.

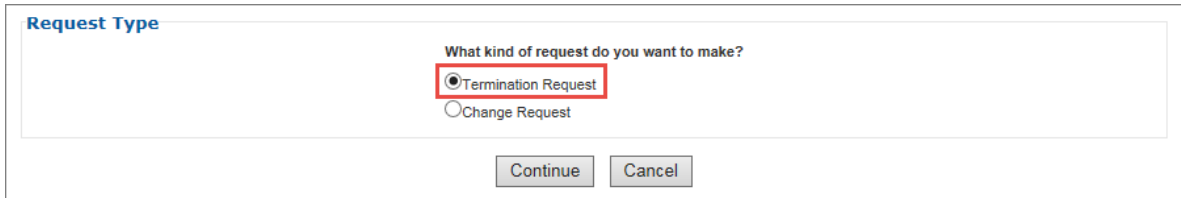
Upon approval by the new AO, the **Contact Information** section will be updated with new AO's information. If the **"Make Primary Contact information same as Authorizing Official"** checkbox was selected before recertification began, that information will also be updated with new AO's information.

The recertification AO login emails will be resent to the new AO automatically.



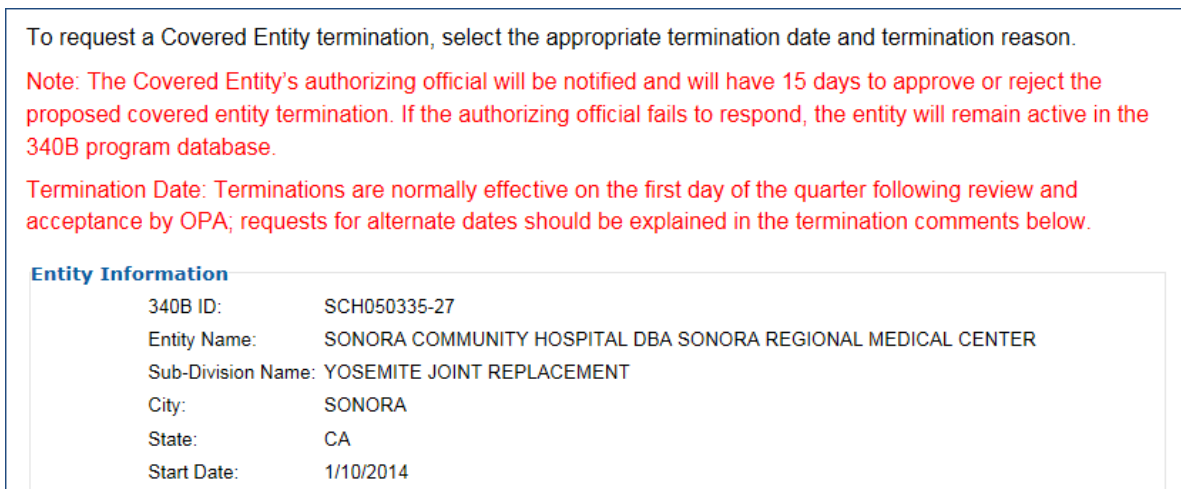
## Termination Requests

- 1) For a termination request, select the **Termination Request** option from the **Request Type** page and click the **Continue** button.



The screenshot shows a web form titled "Request Type". Inside the form, there is a question "What kind of request do you want to make?". Below this question are two radio button options: "Termination Request" (which is selected and highlighted with a red box) and "Change Request". At the bottom of the form are two buttons: "Continue" and "Cancel".

The next page provides instructions for completing the fields on the page and notifies you that the Authorizing Official will have 15 days to accept or reject the request. Failure to respond will cancel the request.



The screenshot shows a web page with instructions for requesting a Covered Entity termination. The text states: "To request a Covered Entity termination, select the appropriate termination date and termination reason." It includes a red note: "Note: The Covered Entity's authorizing official will be notified and will have 15 days to approve or reject the proposed covered entity termination. If the authorizing official fails to respond, the entity will remain active in the 340B program database." Below this is another red note: "Termination Date: Terminations are normally effective on the first day of the quarter following review and acceptance by OPA; requests for alternate dates should be explained in the termination comments below." At the bottom, there is a section titled "Entity Information" containing a table of entity details.

340B ID:	SCH050335-27
Entity Name:	SONORA COMMUNITY HOSPITAL DBA SONORA REGIONAL MEDICAL CENTER
Sub-Division Name:	YOSEMITE JOINT REPLACEMENT
City:	SONORA
State:	CA
Start Date:	1/10/2014

Termination dates are normally effective on the first day of the quarter following approval of the request by OPA.

**Authorizing Official Information**

Has the contact information for the Authorizing Official for this Entity changed? ☒ Yes ☐ No

AO Name: Andrew Jahn


AO Title: PRESIDENT/CEO


AO Phone: 209-536-5012 Ext:


AO Email: ENTITY-AuthorizingOfficialEmail@futrend.com

The authorizing Official represents the covered entity and must be fully authorized to legally bind the covered entity. For many non-hospital covered entities, the authorizing Official is the grantee of record (e.g., Project Director) based upon Federal funding streams. For hospital covered entities, the authorizing Official is usually the CEO/CFO/COO/President/Vice President or equivalent.

Requested Termination Date: 4/01/2015

Termination Reason:    
If none of these reasons apply, stop here and e-mail [ApexusAnswers@340bpvp.com](mailto:ApexusAnswers@340bpvp.com) for additional guidance.

The date the entity became ineligible:  

Last date that 340B drugs were or will be purchased under this 340B ID:  

Termination Comments:

- 1) **Authorizing Official Information:** If the Authorizing Official contact information has changed, select **Yes** and correct that information as necessary.
- 2) **Termination Reason:** Select the reason for the termination request from the drop-down box. If none of these reasons apply, e-mail OPA at [ApexusAnswers@340bpvp.com](mailto:ApexusAnswers@340bpvp.com) for guidance.

Select a Termination Reason

  - DSH percentage below statutory minimum
  - for-profit conversion
  - loss of qualifying grant/support
  - site closure
- 3) **The date the entity became ineligible:** Manually enter the date the entity became ineligible for continued participation in the 340B Program in mm/dd/yyyy format or select it by clicking the calendar icon.
- 4) **Last date that 340B drugs were or will be purchased:** Manually enter the date (mm/dd/yyyy) the entity discontinued, or will discontinue purchasing drugs under the 340B plan or select it by clicking the calendar icon.

**Note:** When a hospital is terminated “**The date the entity became ineligible**” and the “**Last date that the 340B drugs were/will be purchased**” are propagated to all of its active outpatient facilities.
- 5) **Termination Comments:** Enter any pertinent comments regarding the termination.
- 6) Click the  button.

You will now affirm that the information submitted in the change/termination request is truthful and accurate, and that Authorizing Official on record (if you are not the Authorizing Official), for your covered entity will be asked to review and confirm the proposed changes. Refer to [Authorizing and Submitting the Request](#) (page 11) for instructions.

## Authorizing and Submitting the Request

- 1) The **Requestor Signature** page displays.

**Requestor Signature**

☐ By checking this box, I represent that the contents of the change/termination request I am submitting are truthful and accurate. I understand that the authorizing official on record for my entity in the 340B database will be asked to review/confirm the proposed changes, and that I may not submit additional change/termination requests for this entity until the request has been canceled by the authorizing official, allowed to expire by the authorizing official, or accepted or rejected by OPA.

**Requestor**

\* **Name:**

\* **Title:**

\* **Organization:**

\* **Phone:**  Ext:   
(xxx-xxx-xxxx)

\* **Email:**

**Remarks:**

Please include any other information that would be useful to OPA when reviewing the request (e.g., an explanation of any name or address changes). Also, include other relevant comments for OPA to review. Anything entered here will also be seen by the Authorizing Official.

- 2) Check the box in the upper-left corner to affirm that data in the change request is accurate. You also acknowledge that the Authorizing Official will be asked to confirm your proposed changes.
- 3) Complete the required requestor contact information. Also include pertinent comments for OPA to review. Contents in **Remarks** will be made available to the Authorizing Official.
- 4) Click the  button. A screen message thanks you for your submission and notifies you that the Authorizing Official has 15 days in which to accept or cancel your change request before it expires with no action being taken.

Thank you for your submission.

An email has been sent to the covered entity's authorizing official to accept or cancel the change or termination request. If the Authorizing Official does not respond within 15 calendar days, the request will expire without further notification.

For additional assistance, please contact the 340B Prime Vendor Program at 1-888-347-2787 or by email at [ApexusAnswers@340bpvp.com](mailto:ApexusAnswers@340bpvp.com).

If you have any questions, please contact us at:

Office of Pharmacy Affairs  
Mail Stop 8W03A  
5600 Fishers Lane  
Rockville, MD 20857

- 5) Click the  button.

You are returned to the OPA home page. Both you and the Authorizing Official (if you are not the AO), will receive an automated confirmation e-mail, stating that a Change or Termination Request has been submitted. Additionally, the Authorizing Official will receive an email with the subject line “*ACTION REQUIRED: Verification of online 340B Change Request.*” The email will contain a link to the **Change/Termination Request Official Acceptance** page allowing the AO to accept or cancel the proposed changes or termination request.

<b>340B ID:</b>	SCH050335-27	SONORA COMMUNITY HOSPITAL DBA SONORA REGIONAL MEDICAL CENTER
Click the <input type="button" value="Accept"/> button to accept this Change Request Submission.		
Click the <input type="button" value="Cancel"/> button to permanently delete the Change Request Submission.		
<small>NOTE: Change requests cannot be partially accepted at this time. If you are unwilling or unable to accept certain changes, you must cancel the entire request and work with the submitter on a resubmission.</small>		

- Clicking the  button submits the proposed change or termination request to OPA for review and approval. When OPA approves the change or termination request, an approval confirmation email is sent to the Authorizing Official. Copies are sent to the Primary Contact and the requester if they are not the same as the AO.
- Clicking the  button rejects the proposed change or termination request without submitting it to OPA for review and approval.

**Note:** If OPA rejects a proposed change or termination request, a rejection email is sent to the Authorizing Official. Copies are sent to the Primary Contact and the requester if they are not the same as the AO.

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## Other Covered Entities User Guides

[Searching, Viewing, and Exporting Covered Entity Data](#)

[Registering a Covered Entity / Outpatient Facility](#)

[Reviewing the Covered Entities Daily Report](#)

[Recertifying/Decertifying a Covered Entity](#)